Remarks

Entry of the foregoing and reconsideration of the application identified in caption as amended, pursuant to and consistent with the Rules of Practice in Patent Cases, and in light of the remarks which follow, is respectfully requested.

By the present amendment, claims 1 and 17 have been amended and claim 16 has been canceled so that claims 1, 2, 4-15, and 17-27 will remain pending. The amendment to claim 1 finds support in the specification at least at page 21, lines 23 to 25 and claims 16 and 18 of the application as filed. Accordingly, no new matter has been presented by the proposed amendment. Presently, claims 1-4, 11, 12, 14, 15, 17-20 and 27 are being examined and claims 5-10, 13, and 21-26 have been withdrawn from consideration as being directed to non-elected inventions.

Claims 1, 2, 4, 11, 12, and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,300,283 to Prencipe et al. ("Prencipe"). This rejection is respectfully traversed.

Prencipe discloses a toothpaste or dental gel compositions having a pH within the range of about 4 to about 9 (column 2, lines 17-18). The compositions of Prencipe may contain a polymeric thickening agent containing acid groups (column 4, lines 18-29), however, the compositions are not desensitizing agents. Compositions including a non-polymeric acid having a pH within the claimed range are not disclosed or suggested. Accordingly, withdrawal of the record rejection is respectfully requested.

Claims 1 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 99/52498 to Pashley et al. ("Pashley"). This rejection is respectfully traversed.

Pashley discloses a method of reducing dentine sensitivity and compositions therefore. This method includes (i) applying an effective amount of an acid to a dentine surface to form a treated surface, and (ii) administering an effective amount of an acid oxalate to the treated surface so as to occlude dentinal tubules beneath the dentine surface. The method may optionally include the subsequent application of a suitable bonding agent (page 3, lines 12-15).

The acid treatment can be carried out with any acid etchant that is capable of removing an effective amount of calcium phosphate to an effective depth beneath the dentine surface (page 7, lines 20-22). The acidic oxalate contains an oxalic acid salt and has a pH of 4.0 (page 8, line 27 to page 9, line 7; page 11, lines 13-17).

Pashley is concerned with a method of reducing dentine sensitivity. However, Pashley describes the separate use of an acid followed by administering an acidic oxalate to the acid treated surface, i.e. a two-step process. Pashley clearly distinguishes between the strongly acidic acid etchant and the acidic oxalate which is titrated to a pH of 4.0. Pashley does not provide an incentive to combine the acid etchant and the acidic oxalate. To the contrary, it is demonstrated with reference to Figures 2 to 4 that the acid treatment results in an improved action of the acidic oxalate. If the acidic oxalate is directly applied to the tooth surface, crystals of calcium oxalate form on the tooth surface (page 4, lines 7-9). Only if the tooth surface is first treated with acid etchant the acidic oxalate is able to penetrate within the dentine tubules (page 4, line 23 to page 5, line 2).

It was surprisingly found by the present inventors that compositions according to presently amended claim 1 can be directly applied to the tooth surface and result in the formation of massive plugs which deeply penetrate into the dentinal tubules without the need for an acid pretreatment (page 36, example 8, in particular lines 31-35 in combination with Figures 3 and 5; page 36, line 38 to page 37, line 8 and Figure 6). This is a significant improvement with regard to the method disclosed by Pashley in that a separate acid treatment is avoided.

Pashley does not disclose or suggest compositions including a non-polymeric acid having a pH within the claimed range. Accordingly, withdrawal of the record rejection is respectfully requested.

Claims 1, 2, 11, 12, 14-16, 19, and 20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,568,540 to Asano et al. ("Asano"). This rejection is respectfully traversed.

Asano relates to oral hygiene compositions which prevent and control mouth odor, calculus, plaque and caries and contain active zinc ions and fluoride ions (column 1, lines 5-12). These compositions contain a specific buffering system and have a pH of from about 3.5 to 6.0 (column 2, lines 28-29). A preferred buffering agent is sodium gluconate (column 3, lines 7-9). This buffering agent is used in all examples, i.e. in the examples no acid is used. Asano is not concerned with desensitizing agents.

Asano does not disclose or suggest compositions including a non-polymeric acid having a pH within the claimed range. Accordingly, withdrawal of the record rejection is respectfully requested.

Claims 1, 2, 4, 11-20, and 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,004,538 to Hughes et al. ("Hughes") in view of Asano. This rejection is respectfully traversed.

As noted above, Asano discloses compositions having a pH of from about 3.5 to 6.0 and thus, does not disclose or suggest compositions including a non-polymeric acid having a pH within the claimed range.

Hughes discloses oral compositions which include a dimethicone copolyol anti-plaque agent and a dimethicone copolyol surfactant (column 3, lines 26-28). Depending on the intended use, the compositions may include further components. For instance, denture cleansing compositions can also incorporate an effervescence generator, i.e., a material which in the presence of water releases carbon dioxide or oxygen with effervescence (column 8, lines 4-8). Such effervescence generators typically contain at least one alkali metal carbonate or bicarbonate in admixture with an organic acid (column 8, lines 13-23). Hughes discloses the use of acids only in combination with effervescence generators, i.e., in compositions including an acid and also an alkali metal carbonate or bicarbonate, that is a component which reacts with the acid to form carbon dioxide and thus neutralizes the acid. Although Hughes does not specify the pH of the compositions, it is evident that these compositions cannot have an acidic pH. Moreover, compositions including acid and carbonate or bicarbonate are only stable in solid form because acid and carbonate or bicarbonate will immediately react in the presence of water (column 8, lines 35-37). Hughes does not disclose compositions which include a free acid in combination with a solvent.

For at least the reasons noted above, the proposed combination of Hughes and Asano would not render obvious the presently claimed invention. Accordingly, withdrawal of the record rejection is respectfully requested.

Claims 1, 2, 4, 11, 12, 14-20, and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,352,439 to Norfleet et al. ("Norfleet") in view of Asano and further in view of U.S. Patent No. 5,750,145 to Patell ("Patell"). This rejection is respectfully traversed.

The present invention pertains to compositions for the desensitization of teeth including an acid, an organic polymer, a film-forming agent, and a solvent having the recited properties. It has been found by the present inventors that these compositions deeply penetrate into dentinal tubules. By reaction with dentinal fluid proteins they form massive

plugs and thus reduce the sensitivity of the teeth (see page 20, lines 1 to 8 and 17 to 23 of the present application). To achieve the desired formation of a plug, it is necessary to use acids having protein and calcium precipitating properties. The resulting formation of such plugs is surprising since acids usually have a sensitizing effect rather than a desensitizing effect (see page 20, lines 7 to 8 of the present application).

The inventors have demonstrated that the compositions of the present invention result in the formation of massive plugs which deeply penetrate into dentinal tubules (see page 36, Example 8, in particular lines 31 to 35 in combination with Figures 3 and 5; page 36, line 38 to page 37, line 8; and Figure 6 of the present application) even if the natural pressure of dentinal fluid is simulated. The desensitization agents of the present invention result in a long-lasting desensitization effect.

Formation of these plugs cannot be explained by the mere agglomeration of the polymers contained in the compositions. The experiments of the inventors noted above clearly show that the simultaneous precipitation of polymer, dentinal fluid proteins and calcium is responsible for the formation of the plugs.

In contrast, Norfleet discloses oral compositions, such as a tooth paste, including an effective anti-tartar proportion of polyphosphate, and a desensitizing or tooth pain inhibiting proportion of a tooth pain inhibiting potassium salt (see column 1, lines 54 to 59). Preferably the compositions include a potassium salt of an anionic polymeric polycarboxylate (see column 1, lines 64 to 68). These compositions may additionally contain diphosphonic acids and phosphonoalkane carboxylic acids or their alkali metal salts (see column 2, lines 8 to 12). Copolymers, if initially in acidic form, are neutralized to a pH in the range of 6 to 8, preferably 7 (see column 10, lines 3 to 6). Moreover, the pH of the overall composition is preferably also within the range of 6 to 8, more preferably 6.5 to 7.5 (see column 10, lines 25 to 26). Norfleet theorizes that the presence of potassium ion in the composition aids in desensitizing the teeth in toothpastes and other oral compositions so that the teeth feel less pain when brushed (see column 2, lines 17 to 21). Thus, Norfleet does not teach or suggest compositions having a pH within the claimed range.

According to Norfleet, acid components are neutralized and the pH of the compositions is adjusted to be in the range of 6 to 8. There is no reason to modify the compositions of Norfleet to adjust the pH within the claimed range. The compositions of Norfleet do not posses free acid having protein and calcium precipitating properties.

As noted above, Asano discloses compositions having a pH of from about 3.5 to 6.0 and thus, does not disclose or suggest compositions including a non-polymeric acid having a pH within the claimed range. Asano provides no reason to lower the pH to a value within the claimed pH range.

Patell pertains to stabilized pharmaceutical compositions including gelatin-coated pharmaceutically active dosage units containing a therapeutically active ingredient which is subject to hydrolysis on storage as a result of moisture in the air or in one or more of the components of the dosage unit. Patell is especially concerned with the stabilization of analgesics such as gelatin-coated aspirin tablets (see column 1, lines 5 to 12). Patell is cited for teaching film-forming agents. However, Patell in no way teaches or suggests adjusting the pH of the compositions disclosed by Norfleet in the claimed range. Accordingly, Patell fails to make up for the deficiencies of the Norfleet disclosure noted above.

It is asserted that the present amendment of claim 1 further distinguishes the claimed subject matter over these documents. The claimed compositions include a combination of four components which are all needed to achieve the desired action:

1. The acid is responsible for conditioning the enamel and the dentine surface, respectively. The acid removes dentine debris and abrasives from dentifrices from the openings of the tubules so that the tubules are accessible for the protein and calcium precipitating components as well as for the co-precipitating polymers of the compositions of the present invention. The acid initiates the protein and calcium precipitation.
2. Precipitation is enhanced by the organic polymers having carboxyl and/or hydroxyl groups.
3. The precipitation reaction of the present invention usually requires 15 to 30 minutes. During this time period the tubules are protected by a film which is formed by the film forming agents.

This film protects the precipitation process and can easily be removed by toothbrushing or eating. This film is not needed to block the tubules, rather they are blocked by the plugs formed by the precipitation reaction of the acid and the organic polymers together with proteins and calcium from the dentinal liquor. These plugs are stable for 6 to 15 months.

The desensitizers of the present invention are not comparable with a dentifrice. Typically, a desensitization achieved by the use of a dentifrice only lasts for one day, i.e. a dentifrice has to be used daily.

For at least these reasons, Applicants submit that the proposed combination of Norfleet, Asano, and Patell does not render obvious the present invention. Withdrawal of the record rejection and allowance of all claims is respectfully requested.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is hereby earnestly solicited.

Respectfully submitted,

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/Joseph M. Noto/
Joseph M. Noto
Registration No. 32,163

NIXON PEABODY LLP
1100 Clinton Square
Rochester, New York 14604-1792
Telephone: (585) 263-1601
Facsimile: (585) 263-1600